UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH & ENVIRONMENTAL EFFECTS RESEARCH LABORATORY
OFFICE OF RESEARCH AND DEVELOPMENT
Danelle T. Lobdell, Ph.D.
MD 58-A, Research Triangle Park, NC 27711
Phone: 919-843-4434, Fax: 919-966-7584
Email: lobdell.danell@epa.gov

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To Whom It May Concern:

Enclosed, please find Application for IRB Approval for the following study "An Epidemiologic Health Study of Manganese Exposure in Adult Residents of East Liverpool, Ohio." After discussions with Diane in your office, I would like to provide some context for this study. This is a U.S. Environmental Protection Agency Funded study to San Francisco State University (SFSU). The funded PI on the study is Dr. Rosemarie Bowler. We are submitting this protocol through the UNC IRB because our Human Subjects Review Official does have oversight on this project because the funding mechanism is contract. However, this study is an expansion of a previously completed study by Dr. Bowler's team which was funded as a grant and thus did not have direct oversight from our Human Subjects Review Official. Diane advised me to complete the application as the technical expert of the funder and include the already approved protocol from San Francisco State University IRB and to notify you that the Office for the Protection of Human Subjects at San Francisco State University will be the primary IRB of record for this field study.

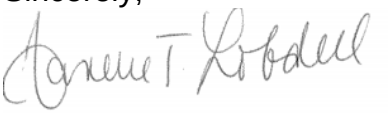
My role in the study is to provide the federal scientific oversight on the study. Because this is a contract, I have directed SFSU on the general exposure and outcomes the study will explore. SFSU has provided the detailed study protocol in which I have advised on and approved. I will be at the study sight during data collection, but will not be engaged in any of the data collection procedures (e.g., consent, questionnaire, neurologic testing, etc.). My role is to provide federal oversight and to answer any questions that relate to the federal government. At the conclusion of the contract, I will receive the data collected from this study (ID only data, no names) at which time will explore secondary data analyses on other potential study questions. The main study questions will be analyzed and interpreted by Dr. Bowler's study team and I will be a co-author on those papers.

The only other two people who potentially could be covered under the UNC IRB are Edward Hudgens who is the project officer on the contract and B. Michael Ray who is the Quality Assurance (QA) officer on this contract. Mr. Hudgens will not be going to the study site nor will he have access to the data. His role is to make sure the U.S. EPA receives all the deliverables as part of this contract and then will pay the contractor

accordingly. Mr. Ray may visit the study site for QA review. There is potential that he may have contact with participants. I have added both names to the IRB.

Please note that a few of the documents have had small minor edits since the approval from SFSU. Dr. Bowler will submit amendments to SFSU's Office for the Protection of Human Subjects for all documents that have had edits after your review. These documents include: consent form, phone recruitment script, sample feedback letter and the study protocol. Please do not hesitate to contact me if you should have any questions.

Sincerely,



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